

1655 #5 NLC
Docket No. JAB-1462

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : PULUSSEN, et al

Serial No. : 09/869,169

Art Unit:

Filed : June 22, 2001

Examiner:

For : GENOTYPING CYTOCHROME EXPRESSION

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Myra H. McCormack

(Name of applicant, assignee, or Registered Representative)

Myra McCormack

(Signature)

January 25, 2002

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Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37
C.F.R. §§1.97-1.98, information relating to the above-identified
application is hereby disclosed. Inclusion of information in
this statement is not to be construed as an admission that this
information is material as that term is defined in 37 C.F.R.
§1.56(b).

Applicant(s) reserve(s) the right to establish the
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information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached);
or

☐ Please charge Deposit Account No. 10-0750/ /
the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached);
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☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ There are no listed references which are not in the English language.


☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/JAB-1462/MHM. This form is submitted in triplicate.

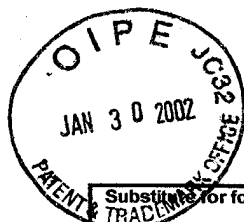
Respectfully submitted,



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DATED: January 25, 2002

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Application Number	09/869169
Filing Date	06/22/2001
First Named Inventor	Paulussen
Group Art Unit	
Examiner Name	
Attorney Docket Number	JAB-1462

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
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	1	Aoyama, T., et al., "Cytochrome P450 hPCN3 a novel cytochrome P450IIIA gene product that is differentially expressed in adult human liver", J.Biol. Chem. 1989 264 :10388-10395	
	2	Barwick J.L., et al., "Trans-species gene transfer for analysis of glucocorticoid-inducible transcriptional activation of transiently expressed human CYP3A4 and rabbit CYP3A6 in primary cultures of adult rat and rabbit hepatocytes" Molecular Pharmacology, 1996 50 :10-16	
	3	Boobis A.R., et al., "Dissecting the function of cytochrome P450" Br. J. Clin. Pharmacol. 1996 42 :81-89	
	4	Cholerton, S., et al., "The role of individual human cytochrome P450 in drug metabolism and clinical response" Trend Pharmac. Sci. 1992 13 :434-439	
	5	Fujii-Kuriyama, et al., "Regulation of CYP1A1 expression" FASEB J. 1002 6 :706-710	
	6	Gorski, J.C., et. al., "Regioselective biotransformation of midazolam by members of the human cytochrome P450 (CYP3A) subfamily", Biochem. Pharmacol. 1994 9 :1643-1653	
	7	Guengerich, F.P. "Characterisation of human cytochrome P450 enzymes", FASEB 1992 6 :745-748	
	8	Hashimoto, H., et al. "Gene structure of CYP3A4, an adult specific form of cytochrome P450 in human livers and its transcriptional control", Eur. J. Biochem. 1993 218 :585-595	
	9	Haehner, B.D. et al. "Bimodal distribution of renal cytochrome P450 3A activity in humans", Mol. Pharmacol., 1996 50 :52-59	
	10	Hoffman, E.C., et al. "Cloning of a factor required for activity of the Ah (dioxin) receptor", Science, 1991 252 :954-958	
	11	Hoyo-Vadillo, C. et al. "Pharmacokinetics of nifedipine slow release tablets in Mexican subjects: further evidence for an oxidative polymorphism", J. Clin. Pharmac. 1989 29 :816-820	
	12	Imataka, H., et al., "Cell specific translational control of transcription factor BTEB expression. The role of an upstream AUG in the 5' untranslated region", J. Biol. Chem. 1994 269 :20668-73	
	13	Itoh, S., et al. "Genomic organization of human fetal specific P-450IIIA7 (cytochrome P-450HFLa)- related gene(s) and interaction of transcriptional regulatory factor with its DNA element in the 5' flanking region", Biochimica et Biophysica Acta. 1992 1130 :133-138	
	14	Jounaidi, Y., et al., "Sequence of the 5'-flanking region of CYP3A5 comparative analysis with CYP3A4 and CYP3A7", Biochem. Biophys. Res. Commun. 1994 205 :1741-1747	

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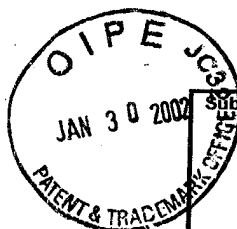
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First Named Inventor	Paulussen
Group Art Unit	
Examiner Name	
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	15	Kormori M. et al. "Fetus specific expression of a form of cytochrome P-450 in human livers", Biochemistry 1990 29:4430-4433	
	16	Lavrijsen K., et al. "Induction potential of antifungals containing an imidazole or triazole moiety. Miconazole and ketoconazole, but not itraconazole are able to induce hepatic drug metabolising enzymes of male rats at high doses", Biochem. Pharmacol. 1986 35:1867-78	
	17	Miller, G.L. "Protein determination for large numbers of samples", Anal. Chem. 1959 31:964	
	18	Nebert, D.W. The Ah locus: genetic differences in toxicity, Cancer, mutation and birth defects. Critical Reviews in Toxicology, 20, 153-174 (1989).	
	19	Renwick, A.G., et al., "The pharmacokinetics of oral nifedipine - a population study", Br. J. Clin. Pharmacol. 1988 25:701-708	
	20	Schellens, J.H.M., et al., "Lack of bimodality nifedipine plasma kinetics in a large population of healthy subjects", Biochem. Pharmacol. 1988 37:2507-2510	
	21	Schuetz, J., et al, "Selective expression of cytochrome P450 CYP3A mRNAs in embryonic and adult human liver", Pharmacogenetics, 1994 4:11-20	
	22	Shimada, T., et al, "Evidence for cytochrome P-450NF, the nifedipine oxidase, being the principal enzyme involved in the bioactivation of aflatoxins in human liver", Proc. Natl. Acad. Sci. USA 1989 86:462-465	
	23	Sogawa, K., et al, "Comparison of DNA-binding properties between BTEB and Spl(1)". J. Biochem, 1993 114:605-9	
	24	Watkins, P.B. "Drug metabolism by cytochromes P450 in the liver and small bowel", Gastroenterology Clinics of North America, 1992 21:511-526	
	25	Wrighton, S.A. et al. "Studies in the expression and metabolic capabilities of human liver cytochrome P450IIIA5 (HLP3)". Mol. Pharmacol. 1990 38:207-213	
	26	Rannug, A., et. al. "Genetic Polymorphism of Cytochromes P450 1A1, 2D6 and 2E1: Regulation and Toxicological Significance", JOEM 37(1) 1995 pp. 25-36	
	27	Jounaidi, Y., et. al. "Detection of a CYP3A5 Allelic Variant: A Candidate for the Polymorphic Expression of the Protein?" Biochemical and Biophysical Research Communication 1996 221:466-470	
	28	Meyer, Urs., et al. "Molecular Mechanisms of Genetic Polymorphisms of drug metabolism", Annual Rev. Pharmacol. Toxicol, 1997, 37:269-96	
	29	Paulussen, Aimee, et. al. "Two linked mutations in transcriptional regulatory elements of the CYP3A5 gene constitute the major genetic determinant of polymorphic activity in humans", Pharmacogenetics, 2000 10:415-425	
	30	Chou, Fang-Chun, et. al. "Genetic polymorphism of cytochrome P450 3A5 in Chinese", DMD 2001 29:1205-1209,	
	31	Kuehl, P., et.al. "Sequence diversity in CYP3A promoters and characterization of the genetic basis of polymorphic CYP3A5 expression", Nature Genetics 2001 27:383-391	

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